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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,500	11/03/2000	Herve Recipon	DEX-0087	6616

7590
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10/22/2002

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/22/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/705,500

Applicant(s)
Recipon et al

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 09/11 6) ☐ Other:

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Response to Amendment

1. Claims 6-11, 13 and 14 have been canceled. Claims 1-5 and 12 have been amended and are under consideration
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. The rejection of claims 1-5, 6 and 12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn. Applicant argues that Lng108 refers to the polypeptide and polynucleotide sequence taught in U.S. patent 5,877,290 and 5,837,498 not GenBank Accession number HSU 25997. This has been considered and found persuasive. Applicant's have also submitted a Declaration by Dr. Nam Kim averring that Lng108 functions as a diagnostic marker for lung cancer and is consistent with serum sample from patients with all stages and grades of tumor.

New Grounds of Rejection

4. Claims 1-5 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-5 and 12 are drawn in part to methods for diagnosing the presence of cancer based on the detection of Lng108, wherein Lng108 comprises a polynucleotide which hybridizes under stringent conditions to an antisense sequence of SEQ ID NO:1 or SEQ ID NO:2. The recitation of "stringent conditions" without the definition of what constitutes the

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physical conditions of stringent hybridization does not serve to limit the structure of the hybridizing polynucleotides. The specification does not set forth any written description of these hybridizing polynucleotides which could vary in length and sequence.

The disclosure of a single species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The instant claims encompass allelic sequences, splice variants, and homologs which are not fully described. There is substantial variability among the species nucleic acids encompassed within the scope of the claims because they are not limited by a common structural feature or a defined function. Thus SEQ ID NO:1 or 2 are not descriptive of variant nucleic acids of SEQ ID NO:1 or 2 or fragments of SEQ ID NO:1 or 2. Thus the claimed method relies on the detection on a large genus of polynucleotides.

A description of a genus of nucleic acids may be achieved by means of recitation of a representative number of nucleic acids, defined by nucleic acid sequences, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. (Reagents of the University of California v. Eli Lilly, 119 F3d 1559, 1569, 43 USPQ2d 1398-1406, Fed. Cir. 1997).

The written description sets forth only SEQ ID NO:1 or 2. Therefore there is no disclosure of a single common structural feature shared by members of the claimed genus. Since the claimed genus encompasses genes yet to be discovered and the polynucleotide encoding SEQ ID NO:1 and 2 do not “constitute a substantial portion” of the claimed genus. Thus, for the reasons set forth above, the specification fails to provide an adequate written description for the methods which rely on polynucleotides which hybridize to an antisense sequence of SEQ ID NO:1 or 2.

5. All other rejections and objections as stated in Paper No. 9 are withdrawn.


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Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


ANTHONY C. CAPUTA
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Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

October 21, 2002